**Community engagement in genomic research: proposing a strategic model for effective participation of indigenous communities.**

**Authors:**

**Olubunmi Ogunrin, Mark Gabbay, Kerry Woolfall, Lucy Frith**

**Abstract**

Community engagement (CE) contributes to successful research. There is, however, a lack of literature on the effectiveness of different models of CE and, specifically, on CE strategies for the conduct of genomic research in sub-Saharan Africa. There is also a need for models of CE that transcend the recruitment stage of engaging prospective individuals and communities and embed CE throughout the research process and after the research has concluded. The qualitative study reported here was designed to address these knowledge gaps and comprised of 36 key informant semi-structured interviews and fifteen focus groups with 50 participants. We interviewed selected stakeholders in genomic research in Nigeria: biomedical researchers, community rulers, opinion leaders, community health workers, and prospective research participants. We explored these stakeholders’ views on their understanding of community engagement, their expectations, experiences, and their opinions on acceptable processes of community consultation in genomic research.

The methodological design, adapted from grounded theory, used the constant comparative method of data analysis; while normative conclusions were made using the symbiotic empirical ethics approach. Data analysis revealed five main themes important for successfully engaging communities in genomic research: effective communication, diversity of community gatekeeping, trust, cultural integration of research, and conservation of the research setting. From these themes, we have developed a four-stage model of community engagement that covers all stages of the research process; namely, the Community Approach, Intermediate phase, Collaboration and Post-research Cordiality model (CICP). This model could be used to improve the integration of CE in genomic research among local communities.

**Key words:** Community engagement, ethical framework, gatekeeping, genomics, sub-Saharan Africa

# **Introduction**

Community engagement (CE) is an ethically important practice for global biomedical research and can be defined as ‘the process of working collaboratively with and through groups of people affiliated by geographic proximity, or special interest, to address issues affecting the well-being of those people [[1]](#footnote-1). CE is a set of practices that help researchers establish and maintain relationships with the stakeholders of a research program. The researcher-stakeholder community relationship transcends individual participation as it engages all members of the community whose interests could be affected by the research [[2]](#footnote-2). Establishing these relationships, the ‘human infrastructure’, is crucial to the success of research, particularly genomic research in sub-Saharan Africa where the collaborative Human Heredity and Health Africa (H3Africa) Initiative, developed to identify major scientific, ethical, and practical issues pertaining to the development of a large-scale genomics research program in Africa [[3]](#footnote-3), is gathering momentum.

There is no doubt that CE strategies and skills can build trust and reduce historical mistrust between researchers, communities and the populations being studied, as well as contribute to the quality of study design, methods, and dissemination of findings [[4]](#footnote-4). When researchers fail to consider the concerns and needs of participants, the research might fail to meet ethical standards and fail to translate potentially beneficial interventions into practice [[5]](#footnote-5). Several models for CE exist including community based participatory research (CBPR), empowerment evaluation, participatory or community action research and participatory rapid appraisal [[6]](#footnote-6). However, a major challenge for the successful implementation of CE is how to identify an appropriate model, if one exists, particularly when conducting research with a culturally diverse population.

Sub-Saharan African society is characterized by ethical multiculturalism, although different ethnic communities do share some common beliefs and moral values [[7]](#footnote-7). African societies have norms and moral values which are often said to be founded on communitarianism [[8]](#footnote-8) [[9]](#footnote-9) [[10]](#footnote-10) and this can be seen in the processes of and procedures for social interactions and decision-making. Within this concept, individual rights and autonomy contribute to the overall community stance. Decisions over research participation or medical treatment, are taken by the community based on communal values of solidarity, brotherhood and common good [[11]](#footnote-11). The community focuses on actions that best promotes its interests and not necessarily those of the individual. The community decision makers, referred to as the ‘gatekeepers’, present the community position on consenting to research [[12]](#footnote-12). They perform this function with the objective of protecting the individual members of the community from exploitation, harm and risks [[13]](#footnote-13). A recent study, however, demonstrated a changing trend in an African country where youths wanted to make the decision to participate in genomic research themselves, rather than have the decision made at the community level. [[14]](#footnote-14).

Genomic research is commonly associated with public fears, often among communities or social groups that have experienced the brunt of social discrimination, stigmatization and isolation in the past. Further, genetic tests on one family member reveal information about the genetic status of other family members. So, who has access to genetic information and material is not only of concern to the individual from whom samples are taken but also their family members.[[15]](#footnote-15).

It was against this background that the National Bioethics Advisory Commission in the United States report, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance,* recommended that researchers should anticipate and disclose potential risks in genetic and genomic research, and consult with community representatives if they believe such risks are possible [[16]](#footnote-16). It has been proposed that all global health research, which includes genomics research, ought to be driven by principles of equity, beneficence and social justice [[17]](#footnote-17).

Thus, finding ways to ensure community representatives are involved in research from the genesis of the protocol through to the publication of the research findings and after, and for researchers to utilize the existing political or social structures within communities to achieve this, has been recommended as a way of protecting communities [[18]](#footnote-18), [[19]](#footnote-19), [[20]](#footnote-20). This is particularly relevant for foreign researchers conducting research in African countries. For example, a case study on aligning community engagement with traditional authority structures in northern Ghana showed that specific pre-existing features of the community greatly facilitated community engagement and the use of traditional engagement mechanisms limits the social disruption associated with research conducted by outsiders [[21]](#footnote-21).  A review of the existing literature published between October 2003 and May 2014 on engagement strategies for genomic studies in Africa concluded that there were several engagement strategies that could support genomic studies in Africa, most of which targeted the early stages of the research process such as recruitment. The findings of this review showed a dearth of information on CE in genomic research in Africa, reinforcing the need to identify effective strategies to engage research participants and their communities beyond the recruitment stage. Especially important is how the views of the local communities should be incorporated into future uses of human biological specimens to determine effective models in African settings [[22]](#footnote-22).

Therefore, this qualitative study explored the perceptions and opinions of stakeholders, (that is biomedical researchers, community leaders, and prospective research participants) on how to effectively engage local populations in genomic research. The data from this study were used to develop a strategic framework that covers all stages of CE and tailored to the participation of indigenous communities in genomic research.

**Methods**

The data reported here are part of a larger qualitative study which explored informed consent and community engagement in genomic research in Nigeria [[23]](#footnote-23). The overall aim of this study was to explore the views of stakeholders on community participation and informed consent processes in genomic research. We interviewed biomedical researchers, community rulers and opinion leaders, and conducted focus group with community members. This paper is based on the findings that pertain to the community engagement process. Other findings have been published elsewhere [[24]](#footnote-24), [[25]](#footnote-25).

***Ethical Considerations***

The research protocol was approved by the Research Ethics Committee in the developing country of the study site (Reference number ADM/DCST/HREC/1792) and Institutional Research Ethics Committee of a UK institution (Reference number IPHS-1415-LB-270). Written informed consent was obtained from all study participants, and verbal informed consent (with evidence of thumb printing) from participants who were not literate. Data obtained were de-identified to ensure participants’ confidentiality. We used pseudonyms to identify participants for reason of confidentiality.

***Study area***

The research project was situated at a tertiary health research institution in a semi-urban community in southwest Nigeria. It is a community of mostly Yoruba-speaking people with Christianity, Islamic or Traditional religious affiliations. Employment is both white-collar (salaried) and indigenous traditional occupations like hunting, farming, and crafts. The community is situated along the trade routes between ports in Niger delta and the Yoruba mainland. The community was selected because it has a defined community leadership, a research institution with biomedical researchers, and prospective research participants which constitute people of interest for this research.

***Study Participants***

Participants were purposively selected from community members attending the research facility. They were categorized, based on their ages, into adults and youths. Adult participants were those above the age of 30 years and married, while the youths were between 18 and 30 years of age. Nine of the 23 youths were married. All study participants reside within the community. Thirty biomedical researchers, engaged in human subjects’ research at a research institution situated in the selected community, participated in key informant semi-structured interviews. Two community rulers, two opinion leaders, and two community health workers (who were recruited reflexively during the study as a ‘member-identified’ category based on responses obtained from biomedical researchers during the interview process) also participated in key informant interviews (face-to-face, semi-structured interviews). The participants were approached personally and through a community contact. Prior to recruitment, they were informed of details of the research. Those who were literate and could read were given an information sheet and opportunity to ask questions about the research. Those who could not read were personally given the details of the research verbally [[26]](#footnote-26), [[27]](#footnote-27).

The summary of study participants is presented in Table 1.

***Focus Groups***

Focus group discussions (FGDs) were conducted with either four to six participants and segmented by age and sex into four categories, namely adult males, adult females, male and female youths. We chose to have separate groups for the males and females, with gender definition in binary terms based on community cultural beliefs and practices, to prevent gender-related authority influence on their group interactions. We wanted to get a deeper understanding of gender inequalities within the community and how these affected their perceptions of community engagement in genomic research. This categorization of participants aimed to minimize paternalism which may prevent women and young persons from freely expressing themselves in a mixed group as noted previously by Fagbemiro and Adebamowo (2014)[[28]](#footnote-28). In addition, the categorization promotes freedom of expression of the FG participants’ cultural beliefs, opinions, and social practices without fear of discrimination.

The topic guide for the FGD (appendix A) contained the following questions: a) would the community want to be part of the conduct of research? b) If not, why? c) If yes, which part of the research would the community want to have an input? d) what does the community expect from researchers who want to conduct research in their community? e) how would you want researchers to go about involving the community in their research? Can you give me examples? f) are there rules or customary norms they need to comply with? Can you give examples?

The FGD was moderated by one of the authors (OO) and a female research assistant with experience in qualitative data collection. There was also a female co-moderator, a staff member of the research institution, from and familiar with the community, for the female FGD sessions. Before each session, all respondents were given a brief explanation of purpose of the FGD and asked to explain what they understood about genomic research and community engagement. Then definitions of genomic research[[29]](#footnote-29) and community engagement[[30]](#footnote-30) were given to them to establish a common starting point[[31]](#footnote-31).

***Interviews***

The biomedical researchers, community rulers, opinion leaders and health workers were interviewed face-to-face and were encouraged to share their experiences from previous research and other relevant life experiences. Interviews were tape recorded and transcribed verbatim by OO. During the process of interacting with data and initial coding, areas that needed further clarification and probing were identified, and these guided subsequent interviews.

***Data Analysis***

The methodological design, adapted from grounded theory [[32]](#footnote-32), used the constant comparative method of data analysis [[33]](#footnote-33), [[34]](#footnote-34). Data were iteratively analysed thematically as the coding framework was developed during the analysis and new areas of questioning were explored in subsequent interviews and FGD sessions to achieve saturation and clarity of data. The coding of the data was aided by Atlas-ti qualitative software. The initial or open coding yielded themes which were subjected to selective coding to identify common and explanatory categories for themes. Deviant cases were identified, discordant views were discussed by the research team, and the quality of data was ascertained by methodological and data or informant triangulation[[35]](#footnote-35), code-recode analysis and reflexivity.

The methodological and informant or data triangulation were used to ensure the credibility of our data by comparing divergence and similarities between the findings from the different data sources and methods. We used both within-method and between-methods approaches for the methodological triangulation of the focus groups and in-depth interviews[[36]](#footnote-36). The within-method involves a comparison of responses from the four FGD categories of participants on one hand, and the three interviewee categories on the other hand. In the between-method approach, we compared the responses obtained using the two different qualitative methods, that is FG and interviews, to detect the similarity of responses and divergent views on the same and different ethical topics using different methods of inquiry[[37]](#footnote-37).

For code-recode analysis, half of the data were open-coded by a member of the research team, and after two weeks a different researcher re-coded same half using a similar coding frame, thereafter the results of the two coding processes were compared for similarities and differences[[38]](#footnote-38),[[39]](#footnote-39). The outcome of the coder reliability index was 96.8 percent which reflected a high degree of similarity of the open coded data[[40]](#footnote-40).

To draw normative conclusions, we used the Symbiotic Empirical Ethics methodological approach[[41]](#footnote-41) [[42]](#footnote-42) to integrate our empirical data with normative analysis. This model emphasizes the relationship between practice and theory in ethical discourse as ‘practice informs theory just as theory informs practice’, stressing that they exist in a symbiotic relationship. It advocates five elements which can be used to integrate empirical data and ethical theory to draw normative conclusions. These elements include: a) setting out the circumstances; b) specifying theories and principles; c) using ethical theory as a tool of analysis; d) building theory; and e) making normative judgements. We set out the ‘*endoxa*’ or circumstances by describing the community leadership structure and appropriate timing for CE from the responses of participants; then specified community engagement principles such as community gatekeeping, interactive planning, and trust, and subsequently used ethical principles such as communitarianism and theories of social capital as tools for analysing the data.

**Results**

*Study participants*

We conducted 36 key informant interviews among (a) 30 biomedical researchers, comprising 16 males and 14 females, (b) two community rulers (with unspecified demographics as it is the customary practice not to divulge the king’s age, but they were males), (c) two community opinion leaders (including one who is a traditional medical practitioner), and (d) two female community health workers. (See table two for demographic information) An opinion leader is a community member recognized by the local government authority to advise on community development issues. Most of the biomedical researchers were involved in clinical science research, with three engaged in laboratory-based genetic studies. Each interview lasted between 45 and 70 minutes. The community rulers, opinion leaders, and community health workers were of Yoruba ethnicity and resided within the community. Fifty community members participated in 15 FGD sessions. Each FGD session lasted between 45 and 75 minutes with a median of 65 minutes. Fifteen focus groups sessions were conducted over a period of eight weeks. The demographics of the study participants are presented in Table 2. All participants were given pseudonyms, selected from a random list of foreign names having confirmed that all participants bear indigenous names, to ensure participant anonymity.

**Community leadership structure**

It is important to be familiar with the community structure and context in order to know how to fully embed community engagement in research. Participants described the community leadership structure, the actors and their roles, and the interactions between the various actors. The community leadership structure has two levels of leadership, namely traditional and political. The civil or political administrative structure is made up of a local government council headed by an elected Chairman who coordinates government-sponsored programs like education, health, road construction, and so on, at grassroots level. The Chairman is assisted by supervisory councillors who oversee these programs, for example there is one for health who supervises the community health centres through the community nurses and midwives, and other health workers. One of the community health workers in her response to the question, ‘who are the representatives to contact before conducting research in the community?’, stated that *‘in that case, you will start from our local government. The HOD of our department (*in the local government council office*) will (*should*) be aware, then readily everybody will be informed.’ (****Felicitas, community health worker).***

The other level is the traditional authority structure which consists of the community ruler referred to as the Oba (king), assisted by the chiefs. In some communities there are chiefs called ‘Baales’ who serve as the representatives of the Oba. Apart from these two levels of leadership, the respondents identified several community group leaders, ‘subsidiary leadership structures’, that can play significant roles in the community. They include religious leaders, leaders of professional groups like farmers, hunters, commercial motorcycle riders (locally referred to as ‘okada’), and market women. This is represented using a schematic diagram – Figure 1, that depicts the social relationships and interdependence between the community leadership and prospective research participants as described in our data.

# **(insert Figure 1) -** Schematic representation of the community social network structure

# **Themes for community engagement**

We will now discuss the main themes that arose from our data: a) Community gatekeeping; b) Trust; c) Effective communication; d) Cultural integration of research; and e) Conservation of the research setting and relate these themes with four stages of proposed framework for community engagement developed from our data as illustrated in Table 3.

***Community gatekeeping***

The concept of community gatekeeping is an integral part of CE. The community leaders are seen as ‘community gatekeepers’ in that they safeguard the whole community from exploitation and harm. Most of the biomedical researchers agreed that the research team must first contact the community leadership was emphasised by the biomedical researchers, community elders, and community members as the proper and appropriate way to initiate CE. Also, community members opined that interacting with the community leadership establishes the legitimacy of the research. The following quotes exemplified this theme:

***Dr Song (biomedical researcher):*** *‘What I mean by approach is that you approach the community, first by talking to the community leaders. You approach the community ruler first, try to brief him and his team, his council of elders what you are planning to do, how the research work will go, that is what I mean by community approach’*

***Elder Jonah (opinion leader):*** ‘*Before you start, it’s important you should see the king. If you see him, you then tell him about it’*

***Elizabeth (adult female):*** *‘They (*referring to the researchers) *need to interact with community leaders, then they* (referring to the community leaders) *will call the community people, then we are sure the research is genuine’*

Some of the biomedical researchers with previous experience pointed out that the gatekeeping responsibility or role was not limited to the rulers or elders, although they were the central point of contact, and there were ‘subsidiary gate-keepers’. The community health workers might also play a special role in research, especially with the need to explain medical or genetic terminology to the people, thus conferring on the health workers a unique educational responsibility.

***Dr Sharp (biomedical researcher):*** *‘And in any community, there are always leaders. There are also health workers in that environment. These are influential people who can talk to the community members’*

The importance of the contribution of community health workers to CE was mentioned by some biomedical researchers. One of them gave an account of his experience of how it was difficult to recruit participants until the community health nurse in charge of the health care facility talked to the people. The biomedical researchers stressed that the health workers were trusted by people because they lived in the community, served as health educators, understood the customs and norms of the community, hence were well positioned to gain the confidence and trust of people. One of the biomedical researchers said, *‘You have to go through somebody the people know, going to them alone they will never agree with you, go through the health worker who will be able to explain what you want to do to them’* ***Dr Mouldy (biomedical researcher).***

Leaders of social or professional groups within the community, such as the market women group, male clubs like the hunters, fishermen, farmers, and religious groups and so on, were also identified as ‘subsidiary gate-keepers’. The leaders of these socio-professional groups play unique roles by engaging group members in effective communication, thereby giving them a sense of belonging, and encouraging the community to make the research their own. In traditional Nigerian settings, like most sub-Saharan African settings, there is usually a women’s leader called ‘Iyalode’ who serves as the leader of the market women. To create community awareness of research, the women in the community may be reached through the ‘Iyalode’ after the community ruler and elders have permitted the researcher to do so.

***Trust***

Another important theme that emerged is trust. The community members and biomedical researchers agreed that the community would respond positively to genomic research if they were engaged by an individual or people known to and trusted by the community. The people trust their community representatives, the community health workers, community rulers and elders, because these are the people they know.

***Dr Meadows (biomedical researcher):*** *‘People that you know that they trust, they see them as those that are not likely to deceive them, not likely to mislead them. So, you need people that they can believe, that is the traditional rulers, the religious leaders, school teachers, health teachers in communities’*

Two of the community leaders said that if the researcher is trusted by the community leaders, it makes participation and recruitment of community members easier: ***King Brown (community ruler):*** ‘*people are not likely to agree but if we the leaders trust you and talk to them first it will not be difficult*’. One of the biomedical researchers emphasised this point when she said, ‘*If you’re able to convince the leaders, that’s the community entrance, getting into the community, that’s the first thing you have to do and its important in research.’ (****Dr Mendy, biomedical researcher).***

The concept of trust is linked to the fact that researchers are strangers to the community as expressed by this community member, *‘As a total stranger, we will not give our consent, you will need to get someone we know and can trust like our sons, an in-law, someone that we are used to’* ***Charlotte (adult female)***. The ‘strangeness’ is not only in terms of someone who is from outside the community but also denotes the researcher’s non-familiarity with the communal norms and values. Therefore, the researcher should approach the community with the goal of getting to know the community and be known by them.

Though the biomedical researchers indicated that approval of research by the community leaders was crucial, this does not constitute informed consent, as individuals still need to give consent. Similarly, most of the community members opined that the approval of research signified that the researcher has been accepted to interact with the members of the community having received clearance as a trustworthy person, and therefore is able to obtain their consent. Most of the focus group participants said that when researchers engage in local community activities like participating in their religious programs or social events, this creates a friendly bond. This is a process that builds trust and respect for the culture and environment, and demonstrates commitment, genuine regard, respect, and interest in the community by the research team. One of the biomedical researchers agreed to this view expressed by the focus group participants, *‘Forging a relationship with the community ‘most of the time there tends to be a dis-connect between we, the researchers, and the larger community, we need to mingle and really be part of them’* ***Dr Sharp (biomedical researcher).***

***Effective Communication***

The strength of collaboration between community members and researchers is based on effective communication of the research plans, appreciation of who the researchers are and attestation to their integrity. The effectiveness of communicating research details to the community members depends largely on speaking the language the people understand, and this is not so much in the dialect or native language alone but also the techniques or strategies of communication, using body language and ‘slogans’ the people prefer and appreciate. It also involves presentation of benefits of the research in such a way that will appeal to the community, while at the same time reassuring them of the fact that risks, if there are, will be minimal and bearable.

There was agreement among the study participants that community leaders and the health workers are in the best position to do this. They can approach the community in the company of the researcher to pass information to the people. This can be done by calling the people together for a ‘town hall’ meeting or ‘community clinic assembly’ where the community representatives, the community health workers, and the researcher inform the people about the research and clarify any issues. This process encourages the people to make the research their own, as effective communication aids building of trust between the researcher and the community. This is stressed by this biomedical researcher;

***Dr Soul (biomedical researcher):*** *‘After you have done that (after the community approach), there is need for you to address the community at a meeting. So, if the researcher does not know how to speak the local language, you will have to work with a colleague who can speak and understand the language very well. When you speak to them in a language that they understand, they are ready to give you their consent.*

According to the biomedical researchers, this communication should be a two-way dialogue. It is not just a unidirectional process whereby the researcher informs the people of what he wants to do and expects them to comply, but it is a process to get feedback from the community, allays their fears and gives them time to ponder the information they have received before consenting to participate.

***Dr Sandy (biomedical researcher):*** ‘*It will not be a one-way thing whereby the researcher only sees it as an avenue to advance his own academic or research knowledge, but the community also sees it as one of the ways of solving their numerous health challenges’*.

The researchers and community members agreed that benefits of research, and compensation for participants should be discussed during the community engagement process. Regarding communication of benefits and compensation, one of the biomedical researchers suggested that *‘the place of incentives must be discussed as one engages the community’ (****Dr Sandy, biomedical researcher).*** The community members emphasised the role of the town crier in publicising the research in the community. This mode of communication is considered a good way of letting the people know that the community rulers and elders have given their approval to conduct research in the community. The research could also be announced in places of worship or at health centres as stated by an FG participant, *‘the town crier announced to the town people, that is a genuine research, announced in the church, some uses the health centre, then it is genuine, then I will not mind participating’* ***Flora (adult female).***

***Cultural integration of research***

The Focus Group discussants, just like majority of the biomedical researchers, agreed that integrating the cultural norms of the community aids recruitment. The integration of the cultural beliefs of the community into how research is implemented demonstrates respect for the community.

***Dr Mole (biomedical researcher):*** ‘*a researcher should actually become familiar with the beliefs and customs of the society where he or she hopes to carry out research, and then try to address some of these beliefs and taboos’*

Cultural integration may be enhanced by the role of lay members on institutional ethics committees. One of the biomedical researchers pointed out that *‘in the ethics committee, we have a member who is a representative of the community. The community representative will really help us a lot with all these superstitious beliefs and so on. He will be able to enlighten us better’* ***Dr Shaw (biomedical researcher),*** implying that the presence of a community lay member may guide researchers in integrating cultural beliefs into the research design before the interaction of the researcher with the community. With such input from the lay member, the researcher will know what to expect when they ‘*come to the field after the proposal has been given approval by the ethics committee*’ (***Dr Sharp, biomedical researcher)***.

***Conservation of the research setting***

The CE process does not end with the completion of research project. Our findings showed that the community respondents and most of the biomedical researchers expressed the need to conserve and not to ‘spoil the research field’, sustaining a cordial relationship between the research team and community after research is completed. If there is a lack of veracity or trust between the researcher and the community this could make it difficult, if not impossible, to get the community to participate in other research in the future. In addition, the community members expect the researcher or the research team to sustain an ongoing relationship with them.

Once a relationship has been initiated during the process of community engagement, the community sees this as a lasting one, looking forward to further fruitful interaction with the team especially if the research is health-related. Local researchers are expected to show more intimate interest in community matters, serve as a link between them and the scientific world, and provide services that will benefit the community.

**Discussion**

The findings of our study showed that the approval of community leadership, trust and effective communication of research, integration of cultural norms and values, fostering partnership and recognition of roles of subsidiary community gatekeepers are important factors that strengthen CE and contribute to successful implementation of genomic research. From these results, we have developed a model for CE that covers the whole research process from before the research commences to after the research is completed, the Community approach, Intermediate, Community Collaboration and post-research Cordiality (CICP) model. We will now outline the components of this model.

Community Approach: This is the initial and most crucial stage of the community engagement process. A major attribute of the community approach stage is that it creates awareness of the presence of the research team. Approaching the community leadership is a demonstration of respect and was identified in the literature and from our results as one of the four main goals for community involvement in research. This goal is especially important due to differences in social and cultural norms, values, goals, resources and technological understanding between researchers and participant communities. This is consistent with the ethical principle of respect for persons, but in this case respect for the community. Therefore, to show the community leaders respect is to respect the whole community and their beliefs. The relationship between the community leadership and the people reflects the beliefs of the African society with its brotherliness and ‘extended’ family concept. Every member of the community sees himself or herself as belonging to a larger family with the ruler as the father.

This approach of contacting the community leadership as the starting point for community engagement was found by Nyika *et al* in a review of case examples from across Africa (involving Burkina Faso, Mali, Gabon and Tanzania). When engaging diverse communities participating in clinical trials, they noted that ‘in preparation for the clinical trials, several meetings with the communities were scheduled. At these initial meetings, information about objectives, methodology, potential risks/benefits and importance of anticipated findings of the intended clinical trials was provided’ [[43]](#footnote-43). Establishing contact with the community leaders is also seen by the community as the proper and acceptable method of communicating with the whole community on issues of great importance like research and health services provision. This phase, also referred to as community entry by some authors [[44]](#footnote-44), [[45]](#footnote-45), [[46]](#footnote-46), is therefore very important and must be well planned and executed by the research team.

We argue that the dynamics of the community approach by a researcher utilises a form of social capital. Social capital theory refers to resources inherent in social relations and networks that facilitate collective action. These networks include links, shared values and understandings that enable individuals and groups within a community to trust one another and work together towards a common good. In social capital theory, three main dimensions of social networks have been described: a). *Bonding:* as exemplified by strong family ties and characterized by trust and reciprocity. Stronger bonding can however limit or restrict an individual to his circle without allowing for interaction outside the circle. The advantage of bonding is that there is a strong reciprocity among members, systems with strong mutual obligations can be typical of African communitarianism; b). *Bridging:* The information and knowledge traded between groups allows the community to benefit from a diversified social endowment accumulation and therefore greater social capital, contributing to the wealth of the community. The lack of bridges may account for differences in development and growth between communities within the same region, and finally c). *Linking:* this indicates ties connecting individuals or groups to people and groups in positions of different political or financial power. This is a vertical relationship, thus allowing individuals or communities to access resources or information from institutions of power, like the relationship between community leaders and the community health workers [[47]](#footnote-47), [[48]](#footnote-48).

Therefore, the researcher uses the bonds between the community leaders and members as an avenue for community entry. For example, Tindana and colleagues in their Ghanaian study showed that specific pre-existing features of the community greatly facilitated community engagement and the use of traditional engagement mechanisms limits the social disruption associated with research conducted by outsiders [[49]](#footnote-49).

The building of trust in the genomic research process commences from the point the researcher contacts the community. It has been stated that ‘trust is everything’ in effective engagement of people [[50]](#footnote-50), and it is the foundation for the success of genomic research and governance of biobanking [[51]](#footnote-51), [[52]](#footnote-52), [[53]](#footnote-53), [[54]](#footnote-54). Similarly, at this stage, the people trusted their leaders to safeguard them and entrust their well-being into the hands of the community leadership, thus they expected the community leaders to scrutinize researchers, who in turn must earn the trust of the leaders. The people expected researchers to be truthful and keep to their promises. It demands demonstration of the virtue of fairness, respect and transparency on the part of the researcher [[55]](#footnote-55), [[56]](#footnote-56). These principles extend to the relationship between the leadership and the people as well. That is, the community members also expect truth-telling and honesty from their own representatives.

Once the initial phase of the community approach is completed, then the researcher can ‘enter the community’. After the researcher has approached, presented himself and gained the trust of the community leadership they will be able to interact with the community. This leads to the next stage of CE which we have called the intermediate phase.

The Intermediate phase: This is the stage of setting up the research. It commences when the researcher has gained the trust of and has had sustained the interaction with the community leaders.The researcher can strengthen its interaction with the community by setting up community advisory boards (CABs) during this phase. The CAB is a group of people representing the community targeted for research who liaise between the research team and that community. The board has the potential of strengthening the science of research study through improving informed consent materials and procedures, enhancing recruitment procedures, and managing the research-related risks to participants and their community during the research process, and all these are instrumental goals of CE[[57]](#footnote-57). This phase precedes the ‘town hall meeting’ where contact is made with community members. During this phase, there is deeper interaction with community representatives and trust is sustained by disclosure of what research entails, including disclosure of possible risks and benefits, genuine consideration of the cultural beliefs of the people, how these can be integrated into the research to prevent or minimize conflicts as much as possible and preparation for effective communication of the research plans to the people. It is important for researchers to disclose details of research to forestall any possible conflict and distrust of science among the public. Public distrust has done great damage to scientific research in the past and present. The Tuskegee syphilis study[[58]](#footnote-58) among the African Americans that began in the 1930s exemplified this [[59]](#footnote-59), [[60]](#footnote-60), [[61]](#footnote-61).

Community Collaboration: Achieving and fostering collaboration of community members during research is important to the successful implementation of genomic research. In the context of the community-researcher interaction and collaboration, social capital theory discussed above is also applicable to this stage. As a cordial relationship develops between the researcher and the community, the researcher gradually becomes integrated into the community, in other words, gets ‘bonded and linked’ to the people. Based on this newly formed relationship, the researcher begins to share in the community’s beliefs and cultural norms, and the community no longer sees them as a stranger because of the relationship that has developed. The radius of trust between the community and the researcher becomes shorter. The radius of trust refers to the mechanism that facilitates cooperation among individuals, the circle of people among whom cooperative norms are operative. This infers that the closer a researcher gets to the people, not just in physical terms of distance but in the context of social integration, the shorter the radius of social interaction, and the higher the likelihood of gaining the trust of the community. The researcher must be in the radius of trust to effectively engage the community otherwise they remain an ‘outsider’.

This cultural integration of the researcher reduces the risk of conflict and enhances the acceptability of research among members of the community[[62]](#footnote-62),[[63]](#footnote-63). High integration and high linkage interact with one to another to produce social opportunities and resources [[64]](#footnote-64). Integration is a process that develops intra-community ties, the more intensive the social ties and generalized trust within a community are, the higher the endowment of this form of social capital. Extra-community networks can be built between two or more different communities [[65]](#footnote-65), [[66]](#footnote-66). Therefore, community engagement and its benefits are not possible if researchers do not take steps to understand the community they are engaging with. Engagement based on community collaboration, and meaningful community participation in research extends beyond physical involvement to include generation of ideas, contributions to decision-making, and sharing of responsibility. On completion of research, there is the post research cordiality which is discussed next.

Post-research cordiality: is the last stage in our community engagement framework. This stage is often overlooked. It comprises of the last phase of the research and prepares the research field for subsequent research projects. The review of the existing literature on community engagement strategies for genomic studies in Africa by Tindana *et al* (2015), emphasised the need to identify effective strategies that will engage participants and communities beyond the recruitment stage [[67]](#footnote-67). Most of the biomedical researchers said that sustaining cordial relationship with the community after the research has additional benefits for future consenting for further research, feedback of results and implementing the research findings in practice. Thus, ensuring any benefits of the research are available for the community.

**Proposed Model for Community Engagement in Genomic Research**

The views of our study participants, stakeholders of genomic research, led us to develop a model (see figure 2) of what actions and preparations are needed to achieve effective community engagement for sub-Saharan African communities in genomic research. This is particularly germane considering that the recent ethics and governance framework for best practice in genomic research and biobanking in Africa by the H3Africa Working Group on Ethics acknowledged that community engagement must be an integral part of all genomic research and biobanking in Africa. This emphasized that researchers should take time to become fully engaged with the community but failed to offer a feasible strategic framework for this in the African setting. Importantly, our model shows how community leadership and social structures are key features and outlines the practical steps that need to be undertaken: discerning the community stakeholders, embedding the research strategy in the social context, and establishing and maintaining a presence in the community.

We compared our model with other models to determine its comprehensiveness. We believe our four-stage model satisfies the CLEAR model of Pratchett *et al* (2009) in which he proposed that research participation is most effective where citizens:

* Can do – that is have reasons and knowledge to participate (addressed by the community approach and intermediate stages in our model)
* Like to – that is have a sense of attachment that reinforces participation (similar to community integration or collaboration stage in our model)
* Enabled to – that is are provided with opportunity for participation (corresponds to community collaboration stage in our model)
* Asked to – that is they are mobilized through public agencies and civic channels (linked to community collaboration or integration in our model), and
* Responded to – that is they see evidence that their views have been considered (similar to community integration or collaboration in our model) [[68]](#footnote-68).

***(insert Figure 2)*** Proposed strategic framework for Community engagement in genomic research

Similarly, these four stages reflect the foundational features identified by Kolopack et al[[69]](#footnote-69) in their study [[70]](#footnote-70). Brenner and Manice (2011), in their attempt to simplify frameworks for community engagement, identified three stages of community engagement which constitute a continuum. First stage is *community consultation* followed by *community participation or community based participatory research* (CBPR), and lastly *community consent* [[71]](#footnote-71).We compared the stages of their model with our proposed model in Table 4.

The differences between our proposed model and Brenner’s are a) Brenner’s model lacks a clear distinction between community consultation and community participation; and b) post-research community engagement is absent. Brenner’s model does not reflect some of the core principles of community engagement proposed by the CDC (2011)[[72]](#footnote-72) which are present in our proposed model. We demonstrate the similarities between our proposed model and the nine principles of community engagement by the CDC (2011) [[73]](#footnote-73) in Table 5.

Our model, the CICP, is a guide for researchers so that every key aspect of community engagement is covered when conducting genomic research. We recommend a document, as represented in Figure 3, that itemizes the components of each phase as tick boxes to aid genomic researchers in the community engagement process. Also, national health regulators and research ethics committees can incorporate this four-phase approach in their ethical guidelines, such as the national or regional ethics code, and make it an integral part of the requirements for conduct of genomic research and biobanking. Although this research was not focused on COVID-19 infection, this strategic framework may be potentially and practically useful for engaging communities in COVID-19 research during this pandemic to promote acceptability of vaccine and fostering trust between scientists and communities.

***(insert Figure 3)-*** Proposed document for phased implementation of community engagement in genomic research

Researchers should address how they would engage participating communities at each phase in their protocols. By so doing, they can demonstrate that they have given due consideration to the potential ethical issues they may encounter before contacting the community leaders. Thus, they will be better prepared for the engagement process. Ethics committee could facilitate this by requiring it as part of the protocol submission process. We recommend that a post- research report on the impact of research on the community, debriefing and feedback from the community members should be made compulsory as part of requirements for researchers when completing their projects to forestall distrust and strengthen the post research cordiality phase.

The limitations of this study include: firstly, the research was conducted within a sub-region of the country which implies possible differences in the cultural practices when compared with other regions within the country and sub-Saharan African countries. However, we opined that the communalism ethos common to the sub-Saharan African indigenous communities would make our proposed model applicable to conduct of genomic research in these communities and allows for modifications to incorporate other cultural peculiarities. Secondly, as is common to qualitative research, the findings of our study are based on purposive sampling hence are not easily generalisable. We hoped that our study would stimulate surveys of a more representative research population to corroborate our findings.

**Conclusions**

To achieve the goals of community engagement in genomic research in Africa, a model that incorporates the basic elements of what the indigenous communities consider to be important is needed. We proposed a four-stage strategic framework, namely; community approach, intermediate phase, community collaboration or integration and post-research cordiality, as an effective community engagement process for implementation of genomic research in indigenous communities.

**Table 1 Summary of all study participants**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S/N | Participants’ category | Sex distribution | | Total |
| Female | Male |
| 1. | Community members (FG participants) | 24 | 26 | 50 |
| 2. | Community rulers | 0 | 2 | 2 |
| 3. | Community/opinion leaders | 1 | 1 | 2 |
| 4. | Community health workers | 2 | 0 | 2 |
| 5. | Biomedical researchers | 14 | 16 | 30 |
|  | Total | 41 | 45 | 86 |

**Table 2 Demographics of the biomedical researchers and FGD participants**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Biomedical researchers** | | | | |
|  |  | Frequency |  | |
| Age distribution | ***Male***  31-40 years  41-50 years  51-60 years  ***Female***  31-40 years  41-50 years  51-60 years  ***Total***  31-40 years  41-50 years  51-60 years | 8  6  2  11  3  0  19  9  2 | ***Male***  Mean: 42.4 (SD 6.2)  Median: 40.5  Range: 35-56 years  ***Female***  Mean:37.5 (SD 3.1)  Median: 38  Range: 33-43  ***Total***  Mean: 40.4 (SD 5.4)  Median: 39.5  Range: 33-56 years | |
| Sex distribution | Male  Female | 16  14 |  | |
| **FGD participants** | | | | |
| *Categories* | *Age ranges* | *Frequency* | *Educational levels* | |
| Adult males | 35-64 years | 12 | Nil education  Home tutoring  Primary  Secondary  Tertiary | 0  0  3  5  4 |
| Adult females | 36-58 years | 11 | Nil education  Home tutoring  Primary  Secondary  Tertiary | 1  1  5  1  3 |
| Youth males | 20-30 years | 13 | Nil education  Home tutoring  Primary  Secondary  Tertiary | 4  0  4  3  2 |
| Youth females | 19-29 years | 14 | Nil education  Home tutoring  Primary  Secondary  Tertiary | 4  1  2  4  3 |

**Table 3 Four-stage proposed model for community engagement in genomic research.**

|  |  |  |
| --- | --- | --- |
|  | Stages | Themes applicable to stage |
| 1. | Community approach  (Before the research begins) | Community leadership, Diversity of gatekeepers, Trust, Community leaders as ‘local ethics committee’, |
| 2. | The Intermediate  (Setting the research up) | Effective communication, Trust |
| 3. | Community integration  (During the research) | Effective communication, Cultural Integration, Trust |
| 4. | Post-research cordiality  (After the research ends) | Trust, Conservation of research field |

**Table 4: Comparison of Brenner’s model and our proposed model of community engagement (CICP)**

|  |  |  |
| --- | --- | --- |
| ***Brenner’s stages*** | ***Components*** | ***Proposed model (CICP)*** |
| Community consultation | Formal dialogue or partnerships between researchers and the community regarding research designs and methods, may take place through focus group, town hall meetings or CABs | This is akin to community approach stage. The dialogue through focus group or town hall meetings occurs in the community collaboration stage in our model. |
| Community participation or CBPR | Equitable involvement, dialogue and exchange between researchers and community representatives in all aspects of the research process, encourages identification and establishment of the social relevance of the research and respect for the community’s culture. | This is similar to the stages of intermediate and community integration or collaboration. |
| Community consent | Solicit permission to conduct study through a formal consultation, agreements and participation | This is akin to community collaboration, although we prefer to use ‘community approval’ rather than ‘community consent’ as community consent does not in any way take away from the importance of the individual research participant’s consent. |

**Table 5: Comparison of CICP with the Nine principles of Community Engagement by CDC**

|  |  |  |
| --- | --- | --- |
| ***Stages*** | ***Principles of community engagement*** | ***Corresponding stages in CICP*** |
| Before starting to work with community: | 1.Define purposes, goals and population  2. Know the community | Stage of community approach (before the research) |
| Items necessary for community engagement | 3. Go to the community  4. Look for collective self-determination | Intermediate phase (Community entry) |
| Success in community engagement process | 5. Community partnership  6. Respect community diversity and culture  7. Mobilize community assets and develop capacity  8. Maintain flexibility  9. Commitment to collaboration | Principles 5 – 7 are consistent with stage of community collaboration.  Principles 8 and 9 are consistent with post-research cordiality. |

Appendix A

|  |  |  |
| --- | --- | --- |
| S/N | Topic of interest | Question |
| 1. | **Knowledge of genomic research** | Have you ever heard of genomic research?  If yes, could you tell me what genomic research looks at?  If no, (this is what it is - genomic research looks at the human genome which is the complete makeup of the human DNA that predict chances of developing diseases in life or pattern of inheritance of diseases). |
| 2. | **Perception of community participation in research**  ***(we explore how much trust the community has in researchers)*** | What does the community expect from researchers who want to conduct research in the community? Are there rules or customary norms they need to comply with?  Will the community want to be part of the conduct of a research? If not, why? If yes, which part of the research will the community want to have an input? How will you want researchers to go about involving the community in their research? Can you give me examples? |
| 3. | **Impact of cultural and religious beliefs on research participation** | Do you think that religion can affect participation of individuals in research? How does it affect participation?  Does your culture encourage participation in research? Are there cultural practices or norms that affect participation of community members in research? What are these practices? How do they affect research participation? Are there norms that allow or disallow different genders or age groups to participate in research? |

Thank you for choosing to participate and for your time.

1. Centre for Disease Control and Prevention, “Principles of Community Engagement” (Atlanta, GA, 1997). [↑](#footnote-ref-1)
2. Katherine F King et al., “Community Engagement and the Human Infrastructure of Global Health Research,” *BMC Medical Ethics* 15, no. 1 (2014): 84, https://doi.org/10.1186/1472-6939-15-84. [↑](#footnote-ref-2)
3. H3 Africa Working Group, “Harnessing Genomic Technologies Toward Improving Health in Africa : Opportunities and Challenges,” *Http://H3Africa.Org/About/White-Paper*, no. January (2011). [↑](#footnote-ref-3)
4. Barbara L. Brenner and Melissa P. Manice, “Community Engagement in Children’s Environmental Health Research,” *Mount Sinai Journal of Medicine* 78 (2011): 85–97, https://doi.org/10.1002/msj.20231. [↑](#footnote-ref-4)
5. J. Lynch., & M. Mitchell. (2010). Community engagement and the ethics of global, translational research: a response to Sofaer and Eyal. American Journal of Bioethics. 10(8), 37-38. [↑](#footnote-ref-5)
6. E Jamshidi et al., “Ethical Considerations of Community-Based Participatory Research: Contextual Underpinnings for Developing Countries,” *Int J Prev Med* 5, no. 10 (2014): 1328–36, http://www.ncbi.nlm.nih.gov/pubmed/25400893. [↑](#footnote-ref-6)
7. GB Tangwa, “Bioethics: An African Perspective,” *Bioethics* 10 (1996): 183–200. [↑](#footnote-ref-7)
8. Cletus T. Andoh, “Bioethics and the Challenges to Its Growth in Africa,” *Open Journal of Philosophy* 01, no. 02 (2011): 67–75, https://doi.org/10.4236/ojpp.2011.12012. [↑](#footnote-ref-8)
9. A Samuel Jegede, “Understanding Informed Consent for Participation in International Health Research,” *Dev World Bioeth* 9, no. 2 (2009), https://doi.org/10.1111/j.1471-8847.2008.00238.x. [↑](#footnote-ref-9)
10. GA Ogunbanjo and D Knapp van Bogaert, “Communitarianism and Communitarian Bioethics,” *South African Family Practice* 47, no. 10 (2005): 51–53. [↑](#footnote-ref-10)
11. GB Tangwa, “The Traditional African Perspective of a Person: Some Implications for Bioethics,” *Hastings Cent Rep.* 30 (2000): 39–43. [↑](#footnote-ref-11)
12. Ayodele Samuel Jegede, “What Led to the Nigerian Boycott of the Polio Vaccination Campaign?,” *PLoS Medicine* 4, no. 3 (2007): 417–22, https://doi.org/10.1371/journal.pmed.0040073. [↑](#footnote-ref-12)
13. Samuel Jegede, “African Ethics, Health Care Research and Community and Individual Participation,” *Journal of Asian & African Studies (Sage Publications, Ltd.)* 44, no. 2 (2009): 239–53, https://doi.org/10.1177/0021909608101412. [↑](#footnote-ref-13)
14. O. Ogunrin et al., “Relative Solidarity: Conceptualising Communal Participation in Genomic Research among Potential Research Participants in a Developing Sub-Saharan African Setting,” *PLoS ONE* 13, no. 4 (2018), https://doi.org/10.1371/journal.pone.0195171. [↑](#footnote-ref-14)
15. Heather Widdows and Sean Cordell, “The Ethics of Biobanking: Key Issues and Controversies,” *Health Care Analysis* 19, no. 3 (2011): 207–19, https://doi.org/10.1007/s10728-011-0184-x. [↑](#footnote-ref-15)
16. US National Bioethics Advisory Commission, “Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries,” 2001, http://bioethics.georgetown.edu/nbac/pubs.html. [↑](#footnote-ref-16)
17. S R Benatar and P A Singer, “Responsibilities in International Research: A New Look Revisited,” *J Med Ethics* 36, no. 4 (2010): 194–97, https://doi.org/10.1136/jme.2009.032672. [↑](#footnote-ref-17)
18. D Kamuya et al., “Engaging communities to strengthen research ethics in low-income settings: selection and perceptions of members of a network of representatives in coastal Kenya,” Dev World Bioethics, 13, no 1 (2013): 10-20, http://www.ncbi.nlm.nih.gov/pubmed/23433404 [↑](#footnote-ref-18)
19. S.F. Morin et al., “Building Community Partnerships; Case Studies of Community Advisory Boards at Research Sites in Peru, Zimbabwe and Thailand,” *Clin Trials* 5, no. 2 (2008): 147–56, https://doi.org/10.1177/1740774508090211. [↑](#footnote-ref-19)
20. Musonda Simwinga, John Porter, and Virginia Bond, “Who Is Answerable to Whom? Exploring the Complex Relationship between Researchers, Community and Community Advisory Board (CAB) Members in Two Research Studies in Zambia,” *Critical Public Health* 1596 (2018): 1–11, https://doi.org/10.1080/09581596.2018.1440072. [↑](#footnote-ref-20)
21. P Tindana et al., “Aligning Community Engagement with Traditional Authority Structures in Global Health Research: A Case Study from Northern Ghana,” *Am J Public Health* 101, no. 10 (2011): 1857–67, https://doi.org/10.2105/AJPH.2011.300203. [↑](#footnote-ref-21)
22. P Tindana et al., “Community Engagement Strategies for Genomic Studies in Africa: A Review of the Literature,” *BMC Med Ethics* 16, no. 1 (2015): 24, https://doi.org/10.1186/s12910-015-0014-z. [↑](#footnote-ref-22)
23. Olubunmi Akindele Ogunrin, “Informed Consent and Community Engagement in Genomic Research” (University of Liverpool, UK, 2018), https://doi.org/https://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.771177. [↑](#footnote-ref-23)
24. O.A. Ogunrin, F Taiwo, and Lucy Frith, “Genomic Literacy and Awareness Ot Ethical Guidance for Genomic Research in Sub-Saharan Africa: How Prepared Are Biomedical Researchers?,” *Journal of Empirical Research on Human Research Ethics* 14, no. 1 (2019): 78–87, https://doi.org/10.1177/1556264618805194. [↑](#footnote-ref-24)
25. Ogunrin et al., “Relative Solidarity: Conceptualising Communal Participation in Genomic Research among Potential Research Participants in a Developing Sub-Saharan African Setting.” Op cit. note 14: p.4 [↑](#footnote-ref-25)
26. Ogunrin, Taiwo, and Frith, “Genomic Literacy and Awareness Ot Ethical Guidance for Genomic Research in Sub-Saharan Africa: How Prepared Are Biomedical Researchers?” op cit. note 24: p.7 [↑](#footnote-ref-26)
27. Ogunrin et al., “Relative Solidarity: Conceptualising Communal Participation in Genomic Research among Potential Research Participants in a Developing Sub-Saharan African Setting.” Op cit. note 14: p.4 [↑](#footnote-ref-27)
28. L Fagbemiro and C Adebamowo, “Knowledge and Attitudes to Personal Genomics Testing for Complex Diseases among Nigerians,” *BMC Med Ethics* 15 (2014): 34, https://doi.org/10.1186/1472-6939-15-34. [↑](#footnote-ref-28)
29. Genomic research looks at the human genome which is the complete makeup of the human DNA that predict chances of developing diseases in life or pattern of inheritance of diseases among populations. It involves scientists analysing the genome and looking for abnormal genes or DNAs that are responsible for causing diseases or abnormal reactions to drugs before they occur. [↑](#footnote-ref-29)
30. Community engagement is the process of, and actions taken by researcher/researchers to get individuals to participate in a research taking place in their community. [↑](#footnote-ref-30)
31. Ogunrin et al., “Relative Solidarity: Conceptualising Communal Participation in Genomic Research among Potential Research Participants in a Developing Sub-Saharan African Setting.” Op cit. note 14: p.4 [↑](#footnote-ref-31)
32. Barney G. Glaser and Anselm Strauss, *The Discovery of Grounded Theory: Strategies for Qualitative Research*, ed. B Glaser and A Strauss (Chicago, Illinois: Aldine, 1967). [↑](#footnote-ref-32)
33. D Silverman, *Doing Qualitative Research; A Practical Handbook* (London: SAGE Publications, 2000). [↑](#footnote-ref-33)
34. D Silverman, *Interpreting Qualitative Data: Methods for Analysing Talk, Text, and Interaction*, 2nd ed. (London: SAGE Publications, 2001). [↑](#footnote-ref-34)
35. Data or informant triangulation involves comparing data obtained from different groups of participants on same issues of interests. In our study, we compared the responses from the various focus group discussants, that is the adult male and female participants, and the female and male youths. The methodological triangulation compared responses obtained on same and different topics from the two methods of inquiry, that is the interview and FGD. [↑](#footnote-ref-35)
36. T D Jick, “Mixing Qualitative and Quantitative Methods: Triangulation in Action,” *Qualitative Methodology* 24 (1979): 602–11, https://doi.org/http://dx.doi.org/10.2307/2392366. [↑](#footnote-ref-36)
37. Helen Streubert Speziale and Dona Rinaldi Carpenter, *Qualitative Research in Nursing : Advancing the Humanistic Imperative*, 4th ed. (Philadelphia: Lippincott Williams & Wilkins, 2007). [↑](#footnote-ref-37)
38. Leslie A. Curry, Ingrid M. Nembhard, and Elizabeth H. Bradley, “Qualitative and Mixed Methods Provide Unique Contributions to Outcomes Research,” *Circulation* 119, no. 10 (2009): 1442–52, https://doi.org/10.1161/CIRCULATIONAHA.107.742775. [↑](#footnote-ref-38)
39. Nicholas Mays and Catherine Pope, “Assessing Quality in Qualitative Research,” *Bmj* 320, no. 7226 (2000): 50–52, https://doi.org/10.1136/bmj.320.7226.50. [↑](#footnote-ref-39)
40. Manfred Max Bergman and Anthony P M Coxon, “FORUM: QUALITATIVE SOCIAL RESEARCH SOZIALFORSCHUNG The Quality in Qualitative Methods 1,” *Social Science* 6, no. 3346 (2005). [↑](#footnote-ref-40)
41. Frith proposed the symbiotic empirical ethics approach for integrating empirical data with normative analysis, this is a naturalistic account of ethical theory that allows for the recognition of circumstances in which ethical decision takes place while not separating the empirical contingencies from the ethical enterprise, thus emphasising practice and theory. Details of this empirical ethical approach is discussed in the paper L. Frith, “Symbiotic Empirical Ethics: A Practical Methodology,” *Bioethics* 26, no. 4 (2012): 198–206, https://doi.org/10.1111/j.1467-8519.2010.01843.x. [↑](#footnote-ref-41)
42. Ibid. [↑](#footnote-ref-42)
43. Aceme Nyika et al., “Engaging Diverse Communities Participating in Clinical Trials: Case Examples from across Africa.,” *Malaria Journal* 9 (2010): 86, https://doi.org/10.1186/1475-2875-9-86. [↑](#footnote-ref-43)
44. V Angwenyi et al., “Complex Realities: Community Engagement for a Paediatric Randomized Controlled Malaria Vaccine Trial in Kilifi, Kenya,” in *Trials*, vol. 15 (England, 2014), 65, https://doi.org/10.1186/1745-6215-15-65. [↑](#footnote-ref-44)
45. V M Marsh et al., “Experiences with Community Engagement and Informed Consent in a Genetic Cohort Study of Severe Childhood Diseases in Kenya,” in *BMC Med Ethics*, vol. 11 (England, 2010), 13, https://doi.org/10.1186/1472-6939-11-13. [↑](#footnote-ref-45)
46. G Okello et al., “Challenges for Consent and Community Engagement in the Conduct of Cluster Randomized Trial among School Children in Low Income Settings: Experiences from Kenya,” in *Trials*, vol. 14 (England, 2013), 142, https://doi.org/10.1186/1745-6215-14-142. [↑](#footnote-ref-46)
47. Luca Andriani, “Social Capital: A Road Map of Theoretical Frameworks and Empirical Limitations,” no. January (2013): 1–26. [↑](#footnote-ref-47)
48. Michael Tzanakis, “Social Capital in Bourdieu’s, Coleman’s and Putnam’s Theory: Empirical Evidence and Emergent Measurement Issues,” *Educate* 13, no. 2 (2013): 2–23, http://educatejournal.org/index.php/educate/article/view/366. [↑](#footnote-ref-48)
49. Tindana et al., “Aligning Community Engagement with Traditional Authority Structures in Global Health Research: A Case Study from Northern Ghana.” Op cit. note 21: p.5. [↑](#footnote-ref-49)
50. Sue Pondrom, “Trust Is Everything - News and Issues That Affect Organ and Tissue Transplantation,” *American Journal of Transplantation* 13 (2013): 1115–16. [↑](#footnote-ref-50)
51. Kaaren Haldeman et al., “Community Engagement in US Biobanking: Multiplicity of Meaning and Method,” *Public Health Genomics* 17, no. 2 (2014): 84–94, https://doi.org/10.1111/j.1365-2958.2010.07165.x.Characterization. [↑](#footnote-ref-51)
52. V Marsh et al., “Beginning Community Engagement at a Busy Biomedical Research Programme: Experiences from KEMRI CGMRC-Wellcome Trust Research Programme, Kilifi,” *Social Science and Medicine* 67 (2008), https://doi.org/10.1016/j.socscimed.2008.02.007. Op cit. note 42: p.25 [↑](#footnote-ref-52)
53. V M Marsh et al., “Working with Concepts: The Role of Community in International Collaborative Biomedical Research,” *Public Health Ethics* 4, no. 1 (2011): 26–39, https://doi.org/10.1093/phe/phr007. [↑](#footnote-ref-53)
54. Ann M. Mongoven and Stephanie Solomon, “Biobanking: Shifting the Analogy from Consent to Surrogacy,” *Genetics in Medicine* 14, no. 2 (2012): 183–88, https://doi.org/10.1038/gim.2011.49. [↑](#footnote-ref-54)
55. Candace Cummins Gauthier, “Moral Responsibility and Respect for Autonomy: Meeting the Communitarian Challenge,” *Kennedy Institute of Ethics Journal* 10, no. 4 (2000): 337–52, http://search.ebscohost.com.ezproxy.liv.ac.uk/login.aspx?direct=true&db=phl&AN=PHL1685626&site=eds-live&scope=site. [↑](#footnote-ref-55)
56. S Holland, “The Virtue Ethics Approach to Bioethics,” *Bioethics* 25, no. 4 (2011): 192–201. [↑](#footnote-ref-56)
57. Megan M. Campbell et al., “Exploring Researchers’ Experiences of Working with a Researcher-Driven, Population-Specific Community Advisory Board in a South African Schizophrenia Genomics Study,” *BMC Medical Ethics* 16, no. 1 (2015): 1–9, https://doi.org/10.1186/s12910-015-0037-5. [↑](#footnote-ref-57)
58. Tuskegee trial was conducted in United States to study the natural course of syphilitic infection among adult male black African Americans without obtaining valid informed consent and they were denied treatment with Penicillin when this treatment became available. [↑](#footnote-ref-58)
59. Global Affairs, *The Integrity of Science*, 2016, https://doi.org/10.17226/21896. [↑](#footnote-ref-59)
60. Z A Bhutta, “Beyond Informed Consent,” *Bull World Health Organ* 82, no. 10 (2004): 771–77. [↑](#footnote-ref-60)
61. A Schulz, C Caldwell, and S Foster, “‘What Are They Going to Do with the Information?’ Latino/Latina and African American Perspectives on the Human Genome Project,” *Health Educ Behav* 30, no. 2 (2003): 151–69, http://www.ncbi.nlm.nih.gov/pubmed/12693521. [↑](#footnote-ref-61)
62. Rinchen Pelzang and Alison M Hutchinson, “Establishing Cultural Integrity in Qualitative Research : Reflections From a Cross-Cultural Study,” *International Journal of Qualitative Methods* 17 (2018): 1–9, https://doi.org/10.1177/1609406917749702. [↑](#footnote-ref-62)
63. Hana Al-bannay et al., “Culture as a Variable in Health Research : Perspectives and Caveats,” *Health Promotion International* 29, no. 3 (2013): 549–57, https://doi.org/10.1093/heapro/dat002. [↑](#footnote-ref-63)
64. M Woolcock and Deepa Narayan, “Social Capital: Implications for Development Theory,” *World Bank Research Observer* 15, no. 2 (2000): 225–49. [↑](#footnote-ref-64)
65. K O’Doherty et al, “From consent to institutions: Designing adaptive governance for genomic biobanks,” *Social Science and Medicine* 73, no 3 (2011): 367-374, http://dx.doi.org/10.1016/j.socscimed.2011.05.046 [↑](#footnote-ref-65)
66. Kieran C. O’Doherty, Alice K. Hawkins, and Michael M. Burgess, “Involving Citizens in the Ethics of Biobank Research: Informing Institutional Policy through Structured Public Deliberation,” *Social Science and Medicine* 75, no. 9 (2012): 1604–11, https://doi.org/10.1016/j.socscimed.2012.06.026. [↑](#footnote-ref-66)
67. Tindana et al., “Community Engagement Strategies for Genomic Studies in Africa: A Review of the Literature.” Op cit. note 22: p.6 [↑](#footnote-ref-67)
68. L Pratchett et al., “Empowering Communities to Influence Local Decision Making” (London, 2009), www.communities.gov.uk/.../localgovernment/pdf/1241999. [↑](#footnote-ref-68)
69. The qualitative study by Kolopack et al described four foundational features of enabling conditions, leadership, core guiding values, and formative social science structure

    Pamela A. Kolopack, Janet A. Parsons, and James V. Lavery, “What Makes Community Engagement Effective?: Lessons from the Eliminate Dengue Program in Queensland Australia,” *PLOS Neglected Tropical Diseases* 9, no. 4 (2015): e0003713, https://doi.org/10.1371/journal.pntd.0003713. Creating enabling conditions and leadership are similar to community approach, establishing core guiding values and formative social science structure incorporates the tenets of the intermediate and community integration/collaboration phases. [↑](#footnote-ref-69)
70. Ibid. [↑](#footnote-ref-70)
71. B Brenner and M Manice, “Community Engagement in Children’s Environmental Health Research.” Mount Sinai Journal of Medicine, 78 (2011): 85-97, DOI. 10.1002/msj.20231 [↑](#footnote-ref-71)
72. Community engagement key function task force of the Centre for Diseases Control and Prevention, Atlanta proposed nine principles for Community Engagement. These include 1. Defining purposes, goals and population and 2. Knowing the community (these two principles apply before starting to work with a community); 3. Going to the community, 4. Looking for collective self-determination – that is helping communities to identify and name their health issues; 5. Community partnership, 6. Respect community diversity and culture, 7. Mobilise community assets and develop capacity, 8. Maintain flexibility – to adapt and change with community issues and needs for long-term collaboration, and 9. Commitment to collaboration – focusing on long-term partnerships to encourage potential for future successful outcomes (the last five principles are necessary for sustaining the success of the engagement process). [↑](#footnote-ref-72)
73. Clinical and Translational Science Awards (CTSA) Consortium’s - Community Engagement Key Function Task Force, “Principles of Community Engagement,” *NIH Publication No. 11-7782*, 2011, https://doi.org/10.1016/j.jenvman.2015.04.014. [↑](#footnote-ref-73)